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EXAMINER

PRIDDY, MICHAEL B

ART UNIT

PAPER NUMBER

3732

DATE MAILED: 06/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,214

Applicant(s)

RICHTER ET AL.

Examiner

Michael B Priddy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 18-24 is/are allowed.
- 6) ☐ Claim(s) 1-13 and 15-17 is/are rejected.
- 7) ☐ Claim(s) 14 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2 and 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Härle (U.S. 5,769,897). Härle teaches an implant which includes a body which may be formed of hydroxyapatite with zones of second material, which may be tricalcium phosphate, wherein the zones of tricalcium phosphate are disclosed as being from .3 to 3mm in size. Härle further discloses that the proportion of hydroxyapatite to tricalcium phosphate is from 5:95 and 90:10. Wherein the hydroxyapatite body includes macropores of from 1 to 5 mm and micropores of size between 10 microns and 300 microns.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Härle as applied to claim 2 above, and further in view of the following. Härle discloses the claimed invention except for all of the zones of tricalcium phosphate being the same size. It would have been an obvious matter of design choice to form the zones of Härle such that they were all the same size, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Härle as applied to claim 3 above, and further in view of the following. Härle discloses the claimed invention except for the tricalcium phosphate zones being randomly distributed throughout the hydroxyapatite body, with some of the zones being located at the surface of the body. It would have been obvious to one having ordinary skill in the art at the time the invention was made to distribute the zones of tricalcium phosphate randomly and at the surface, since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Härle as applied to claim 7 above, and further in view of the following. Härle discloses the claimed invention except for the macropores being spherical and interconnected by being coalesced together. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to form the macropores of Härle as spheres and such that they are interconnected, since applicant has not disclosed that

such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing pores in an implant. In re Dailey and Eilers, 149 USPQ 47 (1966).

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Härle as applied to claim 8 above, and further in view of the following. Härle discloses the claimed invention except for the macropores occupying from 20% to 80% of the total volume of the body. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the implant of Härle such that the macropores occupied from 20% to 80% of the total volume of the body, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Härle as applied to claim 7 above, and further in view of the following. Härle discloses the claimed invention except for the macropores being randomly interspersed throughout the body. It would have been obvious to one having ordinary skill in the art at the time the invention was made to randomly intersperse the macropores of Härle, since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination as applied to claim 8 above, and further in view of Buechel et al. (U.S. 5,868,796). The combination presented in the rejection of claim 8 above teaches all of

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the limitations of the present invention except that the body is provided with surface concavities . Buechel et al. teaches a prosthesis with a biologically inert wear resistant surface. The surface includes a porous coating 22 for promoting bone ingrowth and achieving biological fixation with bone and includes concavities 24 having dimensions between 150 and 500 microns. It would have been obvious to one of ordinary skill in the art at the time of the present invention to form concavities in the surface of the implant of Härle to promote bone ingrowth and achieve biologic fixation with bone.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Härle and Buechel et al. as applied to claim 12 above, and further in view of the following. The combination of Härle and Buechel et al. teaches the claimed invention except for the concavities being rounded. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to form the concavities as taught by Härle in view of Buechel et al. such that they were rounded, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a forming edge in the heating portion or clamp. In re Dailey and Eilers, 149 USPQ 47 (1966).

Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Härle as applied to claim 2 above, and further in view of the following. Härle discloses the claimed invention except for the micropores being randomly distributed throughout the body. It would have been obvious to one having ordinary skill in the art at the time the invention was made to distribute the micropores randomly throughout the

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body since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Härle as applied to claim 15 above, and further in view of the following. Härle discloses the claimed invention except for the micropores occupying 60% or less of the total volume of the body, excluding the volume occupied by the macropores. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the implant of Härle such that the micropores occupy 60% or less of the total volume of the body, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Allowable Subject Matter

Claim 14 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 18-24 are allowed.

Reasons for Indicating Allowable Subject Matter

None of the prior art of record teaches or fairly suggests the method of making an implant as set forth in claim 18.

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Nor does the prior art of record teach or fairly suggest the implant as set forth in claim 14. Härle teaches or fairly suggests all of the limitations of the invention of claim 14 except "the surface concavities are interconnected with the macropores by being coalesced therewith".

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ducheyne et al. (U.S. 5,171,326) teaches improved ceramics including a coating which may contain a combination of hydroxyapatite or beta-tricalcium phosphate. Stone et al. (U.S. 5,624,463) claims a base component including a composition which may be a combination of tricalcium phosphate and hydroxyapatite.

Any inquiry concerning this communication from the examiner should be directed to Michael B. Priddy whose telephone number is (703) 308-8620. The examiner can normally be reached on Mon.-Fri. 8 a.m. - 5 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on (703) 308-2582. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

Michael B. Priddy

Michael B. Priddy

June 10, 2003